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December 22, 2003

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

**Re: Registration of Food Facilities Interim Final Rule;
Docket No. 02N-0276**

Dear Sir or Madam,

The Food Marketing Institute (FMI)¹ is pleased to provide the following comments in response to the Food and Drug Administration's (FDA's) request for feedback on the interim final regulations that were issued pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). 68 Fed. Reg. 58893 (Oct. 10, 2003). At the outset, we commend FDA for the process the Agency is using to develop and issue the final registration regulations. Transparency, notice, outreach to the affected entities concurrent with issuance, issuance as interim final rules, and reasonable enforcement during the initial phases are extremely important to the development of successful regulations and a high degree of compliance with the Bioterrorism Act.

Our primary comment concerns the scope of the facility definition. Retail distribution centers are often comprised of multiple buildings that are considered by the owner or operator of the site to be a single facility. Our members have asked for guidance on determining whether each building must be individually registered or whether the registration requirement can be satisfied by registering the site as a whole. The matter is further complicated by the fact that the individual buildings may not have their own street addresses. The preamble to the interim final registration regulation suggests that businesses look to real estate records because a property line could

¹ FMI conducts programs in research, education, industry relations and public affairs on behalf of its 2,300 member companies — food retailers and wholesalers — in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of \$340 billion — three-quarters of all food retail store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 60 countries.

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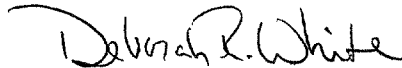
demonstrate that several buildings are on the same lot, and therefore are the same facility. 68 Fed. Reg. at 58905.

Owners/operators should have flexibility in determining whether a site constitutes a single facility. The final regulations should clarify that a single facility may be comprised of multiple buildings and that individual buildings that are part of an overall site need not be separately registered.

* * *

We greatly appreciate the Agency's willingness to receive comments on the registration regulations as evidenced by the fact that they were issued as "interim final" regulations and by FDA's intention to reopen the comment period again in March 2004 to allow the public further opportunity to comment. We look forward to working with FDA to assure that these and related regulations are implemented in a way that provides meaningful additional security for our food supply. Thank you for considering our views.

Sincerely,

A handwritten signature in dark ink, appearing to read "Deborah R. White". The signature is fluid and cursive, with the first name being the most prominent.

Deborah R. White
Associate General Counsel,
Regulatory Affairs